

REMARKS

Reconsideration is respectfully requested in light of the forgoing amendments and the following remarks. Entry of the amendment is respectfully requested since it removes or addresses issues raised in the final Official Action.

Claims 27-31, and 33 are pending. Claims 1-26 and claims 34-36 are directed to a nonelected invention and have been withdrawn from consideration by the Examiner pursuant Rule 142(b). Claims 32, 37, 38 and 39 have been canceled. Claims 27, 29 and 30 have been amended to more clearly set forth the invention. Support for these limitations appears in the specification as follows:

fungus biomass having a dry matter content from 25 to 80%, see page 4 of the specification at lines 6-20;

intact fungus cells, see page 6 line 15;

granular particle size optimal for drying and extraction of a heat- and/or oxygen-sensitive compound under mild conditions, see page 7, lines 6-10 and page 8, lines 1-20;

a storage stable composition, see page 5, lines 16-24; and

dried porous granules, porosity from 20 to 40%, see page, see page 6, line 26- page 7 line 1 and page 21 lines 1-5, Example 25, figs. 5 and 6.

Applicants note that the Examiner's restriction requirement (of 2 February 1998) did not refer to claim 36 as originally filed. This claim covers a process for the isolation of the desired compound from the dried granules. Its status is unclear. It is submitted that claim 36 could now be included herein.

The section 112 rejections

Claims 27-33 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention. Applicants respectfully traverse.

Reconsideration is respectfully considered. There are several places in the specification where there is implied support for "dead". The Examiner's attention is respectfully directed to passages on page 9 at line 29, page 10 at line 15, and page 11 at lines 3, 10 and 12. All of these

passages refer to the killing of the cells, which it is submitted means that the cells are dead. If the Examiner would prefer the term "killed", Applicants will submit a supplemental amendment effecting that change.

Accordingly, withdrawal of the rejection is respectfully requested.

Claims 27-33 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

The claims have been amended to address the Examiner's concerns. In light of these amendments, withdrawal of the rejection is respectfully requested.

Additionally, Examiner's concerns under 37 CFR 1.75(c) relating to claims 32 and 37 have been addressed by the amendments above.

The art rejections

Claims 27, 29, 30-32, and 37 are rejected under 35 USC 102 (e), as anticipated by Rhodes et al. (U.S. Patent 5,759,562). Applicant's respectfully traverse.

Rhodes teaches a composition containing an insecticidal amount of blastophores and a complex nutrient source for application to soil to control soil dwelling insect pests. A blastophore is a spore produced by a budding process along the mycelium or by a single spore. A spore is a resistant body formed by certain microorganisms, a resistant resting cell; a primitive unicellular reproductive body. Spores are not the materials from which one readily extracts "commercial" amounts of intracellular compounds, e.g. β -carotene, Vitamin B-12, etc..

The claims as amended are clearly directed to products which are distinct from those taught by Rhodes et al.. The limitations required by the claims are not by Rhodes et al. expressly or inherently. A spore and nutrient composition teaching is simply not a teaching of an extruded intact fungal cells having a porous structure which facilitates the extraction of intracellular compounds. The claims are directed to an extrudate or granular particles of dead (killed) fungal cells. Additionally, claim 27 specifies that the extrudate is porous (see page 20, line 36, and the first five lines of page 21) and that it is free flowing (see page 19, line 28 and page 20 at line 4). The use of "consist essentially of" further excludes the Rhodes et al. compositions that is directed to live cells. Please also note that the dried granules or extrudate have a structure that allows access, via the pores, of solvent to the dead cells in order to isolate or extract a desired

compound therefrom. Basis for this can be found in the paragraphs spanning pages 6 and 7, on page 14 (first four lines) and on page 20 at line 31.

Withdrawal of the rejection is respectfully requested.

Claims 28-33 and 30-40 are rejected under section 103(a), as being unpatentable over Rhodes taken with Huang et al. and Kyle. Applicant's respectfully traverse.

The three independent claims, as amended, specify that the structure of the extrudate and dry granules are such that it allows, via the pores, access of a solvent to the dead cells so that one can isolate or extract the desired compound therefrom. The same is true of the granular particles of claim 29, although they require drying (to give the dry granules) first.

Further, the present application teaches numerous advantages of granulation techniques in order to efficiently permit extraction of desired compounds in biomass or fungal cell materials. The benefits are illustrated in the Examples, Tables and Figures. In particular, note Tables 2 and 5, Example 25 in contrast to Comparative Example 26 and Figures 5 and 6. Table 5, Example 25 in contrast to Comparative Example 26 illustrate the benefits of the granulated/extruded biomass. Table 2 illustrates the effects of different dry matter contents on the quality of the extrudate. Figure 5 and 6 illustrate the enhanced porosity of the claimed product.

According to the practice of the present invention, granular particles are formed from biomass having a dry matter content from 25 to 80%. Following drying of the particles, desired compounds are extracted therefrom. Granular particle size, water content of the bio mass and its control at various stages of the process are critical to achieving the claimed granular structures which possess numerous advantages. The resultant dried granules permit maximum solvent access for extraction while at the same time avoiding fines or dust from milling that may impede filtration. Granules permit more efficient extractions than larger particles such as flakes. (see the Specification at page 4, lines 6-32; page 7, line 6; page 13, lines 29-32; page 20, lines 33-36). Further, damage to fungal cells is minimized when granule formulations are prepared such as by extrusion, and there is generally no need to disrupt cells prior to extraction of desired compounds. (see page 5, lines 7-9; page 6, lines 10-17; page 14, lines 8-11; page 21, line 7; page 7, line 10). This permits the granular biomass to be storage stable that allows "breaks" in processing, e.g. drying of the extruded granular does not have to be immediately undertaken after its preparation.

None of these advantages (or other advantages referred to in the Specification) are at all evident from the *Rhodes et al.* reference, nor are derived upon combination with the other references.

Rhodes et al. reference is directed to the formulation of a insecticidal blastospore and nutrient composition. Extraction of an intracellular compound is not present in this reference. The parameters that Rhodes et al. teach are directed towards a different end. Survival of an organism is not a disclosed end of the instant invention. Extraction of an intracellular component, in good yield is. Although a granulated form may be present, it is used only so that a nutrient can be co-applied with the fungus, and the cited reference is not at all directed to the extraction of compounds from fungal cell granules. Blastospores are disclosed by Rhodes as fragile.

The *Kyle* reference deals with extraction of compounds from biomass, such extraction is directly from the biomass, there being no mention or use of granule formulations. There is no disclosure of the need to enhance porosity of fungal cells or how to do it.

Huang is directed the treatment of a proteinaceous mass of fungal fibers by rapid dielectric heating in order to reduce the amount of nucleic acid therein. The end product is one that has the texture and chewability of meat. This is not akin to the extraction of Vitamin B-12.

While the *Kyle* reference does deal with the extraction of biomass, it does not suggest the need to enhance cell porosity, employ biomass in extruded granular form, optimize the size of the granular form to facilitate drying and compound extraction, minimize cell disruption, control biomass water content to facilitate its granulation and enhance its porosity. Rhodes et al. do teach extruding fungal blastospore mass to facilitate its intermixing with a complex nutrient medium so that it could be effectively used as an insecticide. It is not clear that Rhodes et al. wish to render its spore more porous and less protected. Huang is directed to a food product which results from lowering nucleic acid content. It is not apparent from the face of these references why they would be combined. There is no common shared problem. Even if there were, the solution discovered by Applicants to the problem they uncovered, is not presentation in the references alone or in combination. The claims reflect the discovered solution.

Further, the specification in the passages referred to above illustrate benefits for the claimed invention that are not expected from the cited references.

It is also submitted that all three of these cited documents are entirely in different fields, and while they all refer to fungal biomass, there the commonality ends: the uses of the biomass are very different. Only the Kyle document is concerned with the production of a particular compound. However, here there is no disclosure of extrusion, or of killing the cells, or preparing granular biomass from which a compound is to be extracted. Barclay refers to animal feeds where ground corn is added before extrusion, and Huang *et al.* deals with reduction of RNA in fungal mycelial fibers which are to be included into foodstuffs. Rhodes *et al.* deals with the insecticidal compositions, and when one includes Rhodes, these four documents could not be more different.

The problem that a skilled man faces in the present application is to efficiently extract the desired compound from a biomass. In the present invention this is achieved by extruding the (already killed) cells into a granular form which is porous. These pores allow access of the solvent to the dead fungal cells and because a large surface area is provided to the solvent the desired compound can be extracted from those cells with greater efficiency. None of the prior art documents extrude, or form granulates, for this reason. Thus the Rhodes, Barclay and Huang documents are clearly in different fields of endeavor, because although they may refer to fungal biomass, either in granules or extruded, these compositions are used for entirely different purposes (indeed each of these documents is in a different subject matter classification). A skilled person when looking to efficiently extract compounds from a biomass would not look to any of these documents because they are in entirely different fields.

Kyle refers to production of PUFAs. However, in order to improve this process, one would not look to insecticidal compositions with live fungi (Rhodes *et al.*) nor to animal feeds (Barclay) nor to textured foodstuffs in which the RNA content has been reduced (Huang). Even starting from the Rhodes *et al.* reference, Applicants cannot see why a person skilled in the art would combine any of the other three references with this one. Again, Rhodes *et al.* refers to live fungi as insecticides, and there is no reason to combine this with a PUFA production process (Kyle), animal feeds (Barclay) or textured foodstuffs for humans (Huang) as all three are in different spheres of technology.

Since a proper *prima facie* case of obviousness has not been established in regards to the claims as amended and further, since the results achieved by the claimed invention would not be expected from the applied art, withdrawal of the rejection is respectfully requested.

CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246152006900. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: July 9, 1999

By: 

Thomas G. Wiseman
Registration No. 35,046
Attorney for Applicants

Morrison & Foerster LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-1888
Telephone: (202) 887-1546
Facsimile: (202) 887-0763